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June 11, 2007

VIA ELECTRONIC FILING

The Honorable Mary Pat Thynge United States District Court 844 N. King Street Wilmington, DE 19801

REDACTED PUBLIC VERSION

Re: Sepracor, Inc. v. Dey, L.P. and Dey, Inc. C.A. No. 06-113-*** (MPT); (Consolidated)

Dear Judge Thynge:

Your Honor may recall that during the April 18, 2007 teleconference in this matter, the Court granted Sepracor's request for a two-week extension of its deadline to respond to Dey's Second Set of Interrogatories on the condition that Sepracor provide "appropriate responses." (Tr. at 13.) The Court also warned Sepracor: "And if they're not, I'll take the measures I deem necessary," and told Dey's counsel: "to the extent ... you have a problem with the answers ... I will try to find some place in my calendar to address it so we can try to deal with the concerns sooner rather than later." (Tr. 13-14.)

On May 11, 2007, Dey apprised the Court by letter that Sepracor's responses to several of Dey's interrogatories were seriously deficient. During a previously scheduled telephone conference on May 14, 2007, the Court requested the parties to hold a meet and confer. The meet and confer was held on May 16, 2007. Unfortunately, the parties were unable to reach agreement on several issues. Moreover, although Sepracor agreed to supplement its responses to a few of the interrogatories, it has not done so yet. (See Ex. A: May 22, 2007 letter to S. Dadio from E. Leff, May 22, 2007 letter from S. Dadio to E. Leff and May 23, 2007 letter from E. Leff to S. Dadio.) This is precisely the type of delay Dey was concerned about when it opposed Sepracor's request for two additional weeks in which to respond.

Dey requests the Court to order Sepracor to provide supplemental responses to Interrogatory Nos. 19, 41 as Sepracor agreed to do on May 16, 2007, almost one month ago. Dey further requests the Court to order Sepracor to fully respond to Interrogatory Nos. 21-24, 28, 29, 43, 44 as more fully discussed below. A copy of Sepracor's responses to Dey's Second Set of Interrogatories is attached as Ex. B.

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Interrogatory Nos. 21-24: This case concerns five patents which were allowed based upon the "unexpected results" of reducing side effects caused by the S(+) isomer of albuterol. Each of these interrogatories requests additional information about the undesirable side effects Sepracor contends result from the use of racemic albuterol. Sepracor's response to Interrogatory No. 21 is discussed as an example of Sepracor's responses to these interrogatories.

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The patents-in-suit claim "a method of treating asthma in an individual with albuterol while reducing the side effects associated with chronic administration of a quantity of an optically pure R(-) isomer of albuterol ..." Dey defined R(-) isomer to mean albuterol which is composed of at least 90% of the R(-) isomer of albuterol and a maximum of 10% of the S(+) isomer of albuterol." This is the definition given for the optically pure R(-) isomer of albuterol in the specification of the patents-in-suit. Sepracor's response, therefore, makes no sense. Dey's interrogatories are clear. Dey requests the Court to order Sepracor to answer Interrogatory Nos. 21-23.

Interrogatory No. 24: This interrogatory requests Sepracor to identify the percentage of patients using racemic albuterol that exhibit each of the side effects identified in response to an earlier interrogatory. In its response, Sepracor invents distinctions that are not created by, nor necessary to, the interrogatory, and then proceeds to object that the distinctions render the interrogatory vague and ambiguous, and therefore, unanswerable.

The interrogatory does not require Sepracor to identify documents, articles, samples investigations, tests, measurements, etc., that speak to REDACTED

The interrogatory simply asks for Sepracor to present any documents, articles, samples, investigations, tests, measurements, etc., that support the percentage of patients using racemic albuterol who exhibit the side effects identified in response to Interrogatory 20. Nor does the interrogatory require a response that distinguishes among and between '

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Sepracor has created these straw men as a way to avoid responding to interrogatory.

The Xopenex label itself identifies the percentages of individuals exhibiting certain adverse effects from racemic albuterol. Dey has simply requested Sepracor identify any additional information of this type along with the supporting documents.

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Interrogatory No. 28: Dey requested the identity of the clinical trials "applicants" undertook "directed toward determining tremorgenicity in humans" identified on page 3 of paper 10 in Application No. 08/691/604. The language Sepracor identified as being vague and ambiguous, "directed toward determining tremorgenicity in humans" was taken directly from the document. Therefore, it is difficult to understand Sepracor's objection. It is not at all clear whether the single study identified by Sepracor is one of the clinical trials the applicants undertook, because the authors of the study are not applicants. Moreover, paper 10 indicates more than one clinical study was undertaken and Sepracor has identified only a single study.

Because the declaration refers to more than one study, Dey has requested Sepracor confirm that the single study it identified is the only study applicants undertook "directed toward determining tremorgenicity in humans."

Interrogatory Nos. 29, 43 and 44: Each of these interrogatories requests Sepracor to identify documents or communications concerning the studies discussed in the specific declarations submitted during patent prosecution. In response, Sepracor invokes Rule 33(d) and identifies hundreds of documents, some of which are hundreds of pages long. It is apparent that most of the documents do not concern the specific studies identified in the declaration inquired about in each interrogatory. This type of document dump is not in keeping with the letter or spirit of Rule 33(d) much less Your Honor's instruction to Sepracor to provide "appropriate responses."

Despite the additional time provided by the Court to respond to Dey's Second Set of Interrogatories and the meet and confer conference between the parties, Sepracor's responses to some of the interrogatories continue to be incomplete, evasive and non-responsive. As explained during the April 18, 2007 teleconference with the Court, Dey continues to be frustrated by what has become a pattern of delays, followed by responses which are non-responsive, thereby requiring Dey to seek the Court's assistance. This creates an unfair burden on the Court and continues to prejudice Dey. Sepracor continues to delay the discovery process by failing to provide appropriate responses to Dey's interrogatories. This time Sepracor has yet to adequately respond to interrogatories, the responses to which were due on April 19.

Dey respectfully requests the Court to order Sepracor to fully respond to the interrogatories identified above by 5:00 PM on June 15, 2007, (approximately two months after the responses were due) and to grant whatever additional relief the Court finds just and proper.

Respectfully,

/s/ John G. Day

John G. Day (I.D. #2403)

The Honorable Mary Pat Thynge June 11, 2007 Page 4

JGD: nml
181406.1
Attachments

cc: Richard D. Kirk, Esquire (by hand delivery; w/attachments)
Jack M. Stover, Esquire (via electronic mail; w/attachments)
Todd R. Walters, Esquire (via electronic mail; w/attachments)
Elizabeth A. Leff, Esquire (via electronic mail; w/attachments)

EXHIBIT A

FLH FROMMER LAWRENCE & HAUG LLP

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May 22, 2007

Elizabeth A. Leff ELeff@flhlaw.com

<u>VIA E-MAIL</u>

Susan M. Dadio, Esq. Buchanan Ingersoll & Rooney PC 1737 King Street, Suite 500 Alexandria, VA 22314-2727

Re:

Sepracor Inc. v. Dey, L.P. and Dey, Inc.

Dear Susan:

At the conclusion of our meet and confer teleconference on Wednesday, May 16, you stated you would send me a written response to the issues raised in Dey's May 11 letter to Magistrate Judge Thynge by Monday, May 21. I did not receive anything from you yesterday. Please let me know if and when you intend to provide the response I was to receive yesterday.

Very truly yours,

Elizabeth A. Leff

//gr

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Susan M. Dadio 703 838 6531 susan.dadio@bipc.com

May 22, 2007

Elizabeth A. Leff, Esq. Frommer Lawrence & Haug, LLP 1667 K Street, N.W. Suite 500 Washington, D.C. 20006

VIA ELECTRONIC MAIL

Re:

Sepracor Inc. v. Dey, L.P. and Dey, Inc.

Civil Action Nos. 06-113-*** & 06-604-*** (Consolidated Cases)

Dear Elizabeth:

Sepracor took its discovery obligations in responding to Dey's second and third set of interrogatories very seriously and believe that its responses are fully responsive and appropriate. We also took very seriously Magistrate Judge Thynge's comments on May 14, 2007 regarding the parties cooperation with one another. It was in this spirit of cooperation that we immediately contacted you on May 14th to propose a date to discuss the issues raised in Dey's letter of May 11, 2007. It was similarly in this spirit of cooperation that we engaged in such a substantial discussion with you about Sepracor's detailed responses and, where applicable, Sepracor's difficulties in attempting to interpret those interrogatories that were viewed as vague, ambiguous, and/or overly broad.

A brief discussion of the specifics for each of the interrogatories addressed in our telephone conference and our follow-up responses are set forth below:

I. Interrogatory No. 19

Dey has alleged that Sepracor's response to Interrogatory No. 19 is insufficient because it does not identify any specific unexpected results, fails to identify any basis for unexpected results, and fails to identify persons in connection with these unexpected results. We completely disagree. As discussed in length during our telephone conference, we identified the information contained in the patents-in-suit and their respective prosecution files. We also listed, by citation including authors, title, and journal citation, a number of publications which identify unexpected results and provide the scientific basis for the unexpected results. Nonetheless, you have requested that we articulate in list form unexpected results upon which patentability was based. While we believe that Sepracor's response to Interrogatory No. 19 was appropriate and without

Elizabeth A. Leff, Esq. May 22, 2007 Page - 2 -

waiving any of Sepracor's objections, we will in the spirit of cooperation supplement our response to provide you with this requested list.

II. <u>Interrogatory Nos. 21-23</u>

Dey has accused Sepracor for "playing word games rather than respond[ing] to these interrogatories. As discussed in our telephone conference, this accusation is completely unfounded. Sepracor can not respond to a contention interrogatory that does not accurately articulate its contention. Sepracor could have appropriately said no more than this in its response. However, Sepracor went above and beyond by informing Dey, in the last two sentences of its response, what Sepracor's contentions are in this regard. During our telephone discussion on this issue, you indicated that you did not read those last two sentences. We trust now that this has been highlighted to you that your concerns with Sepracor's responses to Interrogatory Nos. 21-23 are moot.

III. Interrogatorey No. 24

Dey has asserted that Sepracor's response to Interrogatory No. 24 "is a masterwork of obfuscation." We maintain, as discussed in our call, that it is the interrogatory request itself that is the source of obfuscation. During our discussion on this point that Dey could not precisely articulate what it is seeking by asking this interrogatory. Nonetheless, it is our understanding, after our lengthy discussion in connection with this interrogatory, that Dey is attempting to know if Sepracor is aware of any document or publication that reports a study which may take the results from the limited number of patients in that study and extrapolate those results into an overall general percentage for the population of patients using racemic albuterol. Please let me know if this understanding is correct. If our understanding is not correct, please provide us with a detailed explanation in writing so that we can properly understand the request. Once we are certain that we are both of the same understanding, we will, without waiving any of Sepracor's objections, supplement this response accordingly.

IV. <u>Interrogatory No. 28</u>

Dey has asked a series of questions about Sepracor's response to Interrogatory No. 28. We do not necessarily believe that this is an appropriate forum for Dey to seek additional information that it should either obtain in further requests or in a deposition. Nonetheless, in the spirit of cooperation and without waiving any of its objections including Sepracor's objection to Dey's approach in this regard, we are consulting with our client to attempt to obtain answers to your inquiries and will supplement Sepracor's response accordingly.

Elizabeth A. Leff, Esq. May 22, 2007 Page - 3 -

V. Interrogatory Nos. 29, 43, and 44

Dey objects to all of the information that Sepracor provided to Dey in response to Interrogatory Nos. 29, 43, and 44. However, as discussed during our telephone conference, Dey asked for all of this information when it asked for "each document or communication concerning" (emphasis added) and when it defined the term "concerning" in the overly broad fashion that it did in its instructions and definitions. During our telephone conference, you mentioned that Dey did not know how to ask for the information it was seeking in any other way. However, as we mentioned, Dey certainly knew how to craft an interrogatory request to specifically obtain information about one of Sepracor's studies when this was in fact what it sought to obtain. In this regard, we once again direct your attention to a comparison between Interrogatory No. 28 and Interrogatory Nos. 29, 43, and 44.

Further, during our telephone discussion, you had indicated that we should have been able to interpret what it was that Dey was seeking. As we mentioned, we have walked this dangerous road in the past with respect to responses to Dey's interrogatories to only get burned. In light of this past experience and the seriousness to which we took our obligations in being fully responsive and appropriate with our responses, our respective responses set forth a listing of what it was that Dey asked for in its request.

Additionally, Dey has objected to Sepracor's proper invocation of Rule 33(d). Rule 33(d) was properly invoked because of the undue nature of imposing upon Sepracor what Dey could just as easily obtain on its own. In particular, Dey's instructions provide a whole host of information that is to be provided when a document is "identified." These instructions go way beyond Sepracor's obligations under the Federal Rules of Civil Procedure and an appropriate objection has thus been entered. In its response to Interrogatory Nos. 29, 43, and 44, Sepracor provided the title of the particular documents and the bates number ranges. Sepracor has produced its documents to Dey in tiff images for Dey's purposes of using available technology for holding and searching Sepracor's document production. Dey can therefore just as easily search for the listed documents by title or bates number range and obtain the rest of the identifying material that Dey's instructions set forth. Even if Dey chooses not to use the technology that it has previously indicated that it is using, Dey could also review hard copies of the identified documents which have been produced and obtain the identifying information just as easily as Sepracor. This type of situation is exactly the circumstances under which Rule 33(d) is properly invoked.

Elizabeth A. Leff, Esq. May 22, 2007 Page - 4 -

VI. Interrogatory No. 41

Dey has argued that Sepracor has not fully responded to this interrogatory. We cdisagree. As discussed during our telephone conference, we informed you that there is no response with regard to UK Patent 1,200,886 as Bayer AG never brought this reference to Sepracor's attention. We will also confirm any response regarding UK Patent 1,298,494. In the spirit of cooperation and without waiving any of its objections, Sepracor will then supplement its response accordingly - even if this means that we simply state that there is no response as discussed above.

Sincerely,

BUCHANAN INGERSOLL & ROONEY PC

SMD/lp



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May 23, 2007

Elizabeth A. Leff ELeff@fihiaw.com

VIA E-MAIL

Susan M. Dadio, Esq.
Buchanan Ingersoll & Rooney PC
1737 King Street, Suite 500
Alexandria, VA 22314-2727

Re: Sepracor Inc. v. Dey, L.P. and Dey, Inc.

Dear Susan:

This will respond to your letter of May 22 which was e-mailed to me at 11:45 PM. Dey is disappointed that the letter did not provide Sepracor's supplemental responses, but rather states Sepracor will supplement certain responses. We believe Magistrate Judge Thynge was quite clear when in giving Sepracor an additional two weeks to respond to the interrogatories, she required that Sepracor provide adequate information in its responses. Sepracor's promise to supplement its response rather than actually providing a response is yet another delay in providing to Dey the information it is entitled to. Without taking the time now to respond to everyone of your statements about what was said during the parties' meet and confer conference, I would like to make clear that I disagree with your characterizations. I address each of your follow-up responses below.

<u>Interrogatory No. 19</u>: Please let me know when Dey can expect Sepracor's response. We request it be provided by 5:00 PM on May 25, which is nine weeks after the interrogatory was first propounded.

Interrogatory Nos. 21-23: First, let me correct the record. I never stated that I did not read the last two sentences of Sepracor's response. Indeed, my colleagues and I read the responses several times to try to discern what Sepracor meant by its response. As stated in Dey's May 11 letter to Magistrate Judge Thynge, and as I stated during our meet and confer telephone conference, Interrogatories Nos. 21-23 are very clear. For example, Interrogatory No. 21 requests "of the undesirable side effect(s) identified in response to Interrogatory No. 20, identify each undesirable side effect that Sepracor contends is reduced or eliminated by the administration of R(-) isomer." Interrogatory No. 20 requested Sepracor to identify each undesirable side effect caused through the use of racemic albuterol. In addition Dey defined the R(-) isomer of albuterol to mean "albuterol which is composed of at least 90% of the R(-) isomer of albuterol and a maximum of 10% of the S(+) isomer of albuterol." Accordingly, Dey is asking Sepracor to identify which undesirable side effects Sepracor is referring to when it states "[i]t is Sepracor's contention that an individual or patient obtains a reduction in undesirable side effects through use of optically pure R(-) isomer of albuterol as compared to the undesirable side effects that would be caused through use of racemic albuterol in an amount that would provide

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the same desired effect." I do not know how Dey could be more clear about what is being requested. The same is true for Interrogatory Nos. 22 and 23. If we do not receive an adequate response to Interrogatory Nos. 21-23 by 5:00 PM on Friday, May 25, we intend to seek assistance from the Court.

Interrogatory No. 24: Dey is requesting Sepracor to identify the percentage of patients using albuterol that exhibit side effects. These percentages will likely be based on studies, tests, surveys. For example, Table 2 in the Xopenex label SEP0112136 identifies the percentages of individuals exhibiting certain adverse effects from racemic albuterol. Dey is requesting that Sepracor provide this type of information for all side effects caused through the use of racemic albuterol along with the identity of any documents supporting those percentages.

Interrogatory No. 28: Dey has not "asked a series of questions about Sepracor's response." The issue raised is clear. The response to Office Action referred to in the interrogatory states "applicants" undertook "clinical trials directed toward determining tremorgenicity in humans." In its response, Sepracor identified a single clinical trial performed by individuals other than the applicants. Dey has requested confirmation that this is the only study referred to in the cited Response to the Office Action. Contrary to your statement, Dey is not seeking "additional information" it is simply asking for confirmation that a complete response to the interrogatory was provided given the discrepancy between what was said in the Response to Office Action (more than one trial done by applicants) and Sepracor's interrogatory response.

Interrogatory Nos. 29, 43 and 44: Putting aside your rhetoric, each of these interrogatories requests Sepracor to identify documents or communications concerning the studies discussed in specific declarations. It is apparent that each of the over 500 documents identified by Sepracor does not concern the specific studies identified in the specific declarations referred to in each interrogatory. Moreover, there appears to be a misunderstanding regarding Dey's objection to Sepracor evoking Rule 33(d). Dey's objection to the use of Rule 33(d) did not relate to the information Sepracor provided regarding the identity of each document. Rather it was addressed to Sepracor's apparent position that it is up to Dey to go through some 500 plus documents and determine those that correspond to the studies discussed in the declarations identified in each interrogatory. Sepracor is in a far better position to determine which of the over 500 documents listed by Sepracor are responsive to each of the interrogatories.

Dey continues to believe what is requested in Interrogatory Nos. 29, 43 and 44 is clear. If Sepracor does not provide a response that lists only the documents that concern the specific studies discussed in the specific declarations identified in each interrogatory by 5:00 PM on Friday, May 25, Dey will seek the assistance of the Court.

Susan M. Dadio, Esq. May 23, 2007 Page 3

Interrogatory No. 41: We understand Sepracor's response to be that Bayer AG never brought UK Patent 1,200,886 to Sepracor's attention. With respect to UK Patent 1,298,494, we understand that you will provide a response. Please do so by 5:00 PM on May 25.

Very truly yours,

Elizabeth A. Leff

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EXHIBIT B

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